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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,579	12/06/2005	Hitoshi Niwa	0020-5374PUS1	4814

2292 7590 06/26/2009

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EXAMINER	
CROUCH, DEBORAH	

ART UNIT	PAPER NUMBER
1632	

NOTIFICATION DATE	DELIVERY MODE
06/26/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/532,579	NIWA ET AL.	
	Examiner	Art Unit	
	Deborah Crouch	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,13,14,17,18,20-24,30,32,34-37 and 39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *11,13,14,17,18,20-24,30 and 34* is/are allowed.

6)☒ Claim(s) *32,35-37 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/11/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's arguments filed March 25, 2009 have been fully considered but they are not persuasive. The amendment has been entered. Claims 11, 13, 14, 17, 18, 20-24, 30, 32, 34-37 and 39 are pending.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 32 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 32 is drawn to a process for culturing mouse pluripotent stem cells, which comprises culturing the mouse pluripotent stem cells in a medium comprising leukemia inhibitory factor (LIF), an antioxidant and an inhibitor of adenylate cyclase activity under a condition such that adenylate cyclase activity is inhibited, said process allowing the mouse pluripotent stem cells to proliferate or establish while maintaining the cells in an undifferentiated state, wherein the inhibitor of adenylate cyclase activity is selected from the group consisting of adrenocorticotropic hormone (ACTH), brain natriuretic peptide (BNP), pituitary adenylate cyclase activating polypeptide (PACAP), and a peptide having a physiological activity substantially similar to them.

As stated in the office action mailed November 25, 2008, neither ACTH, BNP nor PACAP have adenylate cyclase inhibitory activity. Thus a peptide having a physiological activity similar to them is not enabled. The rejection provided evidence that at the time of filing ACTH, BNP and PACAP were activators of adenylate cyclase. The rejection is repeated here:

> PACAP, BNP and ACTH, at the time of filing, and contrary to the specification, were recognized by the art to be *activators* of Adenylate cyclase (Gracia-Navarro, page 1069, col. 1, parag. 1, lines 1-3; Schorr, page 5806, col. 2, parag. 1, lines 4-7; and Yasuda, page 127-128, bridg. sent.. While applicant provides evidence that ACTH promotes mouse ES cell colony formation, ACTH functions as Adenylate cyclase activator does not change (specification, page 29, lines 6-19). The same analysis is true for BNP and PACAP.

In the response filed March 25, 2009, applicant did not address this rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-37 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 states:

A process for culturing mouse pluripotent stem cells, which comprises culturing the mouse pluripotent stem cells in a medium comprising leukemia inhibitory factor (LIF), an antioxidant and an inhibitor of adenylate cyclase activity under a condition such that adenylate cyclase activity is inhibited, said process allowing the mouse pluripotent stem cells to proliferate or establish while maintaining the cells in an undifferentiated.

Claim 17 states:

A process for the preparation of a clonal population of undifferentiated mouse pluripotent stem cells, which comprises culturing the undifferentiated mouse pluripotent stem cells in a medium comprising leukemia inhibitory factor (LIF), an antioxidant and an inhibitor of adenylate cyclase.

Claim 35 states the media of claim 11 “further comprises” a differentiation inhibitory factor, a serum replacement and antioxidant. Claim 36 states the method of claim 17 “further comprises” a differentiation inhibitory factor, a serum replacement and an antioxidant. As a first issue, the term “a differentiation inhibitor factor” is broader than LIF. As a second issue, the language of claims 35 and 36 imply the media contains these factors and are then supplemented with the factors. Applicant may mean "the method of claim 11 or 17 where the media comprises serum replacement." This is the only limitation to claims 11 or 17 in claims 35 or 36.

Claims 37 and 39 implies the media of claim 11 is modified further to include LIF, 2-mercaptoethanol, KSR and ACTH or SQ22536. However this does not represent the disclosed invention. The claims need to be amended to state the method of claim 11, where the antioxidant is 2-mercaptothanol and the like the for the other factors specified in claims 37 and 39. However, amending claim 39 to state wherein the adenylate cyclase inhibitor is ACTH will result in a lack of enablement rejection against claim 39. As presently written the media of claim 11 contains both an adenylate cyclase inhibitor and adenylate cyclase activator. This is not representative of the disclosed invention.

The claims are free of the prior art. At the time of filing, the prior art did not teach the culture of pluripotent stem cells under conditions that inhibit Adenylate cyclase activity. Pesce et al provides the closest prior art, but teaches PACAP is an Adenylate cyclase stimulator and promoter the growth of mouse PCG cells, which are not

pluripotent cells. However, Pesce (Ref. CA) in combination with Shamblott et al. (1998) Proc. Natl. acad. Sci, Vol. 95, pp. 13726-13731. may be applied as an obviousness type rejection if the claims are amended to eliminate reference to Adenylate cyclase inhibitors.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch whose telephone number is (571)272-0727. The examiner can normally be reached on M-Fri, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch/
Primary Examiner, Art Unit 1632

June 24, 2009